

REMARKS

A. Status of Claims

Claim 83 has been amended without prejudice or admission to depend from claim 82 instead of claim 80.

New claims 95 to 98 have been added. Support for new claim 95 can be found, e.g., in paragraphs [0057], [0063], [0064], and [00118] of the specification as filed. Support for new claim 96 can be found, e.g., in paragraph [00116] of the specification as filed. Support for new claim 97 can be found, e.g., in paragraphs [0057] and [0058] of the specification as filed. Support for new claim 98 can be found, e.g., in paragraphs [0025], [0061], [0062], and [0063] of the specification as filed.

Once the present amendment is entered, claims 1-4, 6, 11, and 74-98 will be pending, with claims 1-2, 4, 11, 81, 83, 85, 87, and 89 withdrawn from the consideration.

Applicants respectfully submit that claims 3, 6, 74-80, 82, 84, 86, 88, and 90-98 are encompassed by the elected invention (including the elected species).

B. Claim Rejections- 35 U.S.C. § 102

Claims 3, 6, 74, 75, 77, 78, 80, 82, 84, 86, 89, and 91-94 were rejected under 35 U.S.C. §102(b) over the U.S. Patent No. 6,192,882 to Gonda ("the Gonda patent").

The rejection is respectfully traversed.

The Gonda patent is directed in part to using color, taste and/or smell as a means of monitoring aerosol delivery. *See the Gonda patent, columns 7 and 8.*

Independent claims 3, 6 and 84 recite, in part, a step of "associating the scent or scent

profile with the identity or source of the pharmaceutical dosage form.”

Applicants respectfully submit that the step of “associating the scent or scent profile with the identity or source of the pharmaceutical dosage form” as recited in independent claims 3, 6 and 84 is not described in the Gonda patent. Accordingly, Applicants submit that the Gonda patent cannot anticipate independent claims 3, 6 and 84.

Independent claim 80 recites, in part, a step of imparting a scent or scent profile to the dosage form, wherein the scent or scent profile imparted to the dosage form “is in an amount or concentration which ... is below the human olfactory threshold of the scent or scent profile.”

Applicants respectfully submit that the step of imparting a scent or scent profile to the dosage form, wherein the scent or scent profile imparted to the dosage form “is in an amount or concentration which ... is below the human olfactory threshold of the scent or scent profile” is not described in the Gonda patent. Accordingly, Applicants submit that the Gonda patent cannot anticipate independent claim 80.

For the foregoing reasons, withdrawal of the anticipation rejection of independent claims 3, 6, 80 and 84, and their dependent claims, is respectfully requested.

C. Claim Rejections- 32 U.S.C. § 103

Claims 3, 6, 74-80, 82, 84, 86, 88, and 90-94 were rejected under 35 U.S.C. § 103(a) over the combination of the Gonda patent and U.S. Patent No. 5,855,907 to Peyman (“the Peyman patent”). The Peyman patent was relied upon by the Examiner for its purported teaching of an aerosol opioid formulation. *See Office Action, page 4.*

The rejection is respectfully traversed.

Applicants respectfully submit that the combination of the cited references does not teach or suggest the step of “associating the scent or scent profile with the identity or source of the

pharmaceutical dosage form” as recited in independent claims 3, 6 and 84.

Applicants further submit that the combination of the cited references does not teach or suggest the step of imparting a scent or scent profile to the dosage form, wherein the scent or scent profile imparted to the dosage form “is in an amount or concentration which ... is below the human olfactory threshold of the scent or scent profile” as recited in independent claim 80, at the very least because the primary reference relied upon by the Examiner uses human olfactory senses, e.g., to “determine the difference between” the smell of the sensory compound and the smell of the carrier or active compound. *See the Gonda patent, column 3, lines 45-55.*

For the foregoing reasons, withdrawal of the obviousness rejection of independent claims 3, 6, 80 and 84 and their dependent claims is respectfully requested.

CONCLUSION

An early and favorable action on the merits is earnestly requested. According to currently recommended Patent Office policy, the Examiner is specifically authorized to contact the undersigned by telephone in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
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